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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,451	03/11/2005	Giorgio Mari	7B901-004US1	2728

69713 7590 01/12/2011
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EXAMINER	
KIM, SUN U	

ART UNIT	PAPER NUMBER
1777	

NOTIFICATION DATE	DELIVERY MODE
01/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/527,451	MARI ET AL.	
	Examiner	Art Unit	
	JOHN KIM	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19, 21-33* is/are pending in the application.

4a) Of the above claim(s) *12-19 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/10 has been entered.

2. Claims 12-19 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/24/08.

3. Claims 22 and 25 are objected to because of the following informalities: "bypass" on line 14 of claim 22 should be changed to "third". "the second satellite container" on lines 11-12 of claim 25 should be changed to "the second secondary receptacle".

Appropriate correction is required.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 21-25, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al (US Patent No. 5,128,048) in view of Nishimura (European Patent Application No. 0591980 A2).

Regarding claim 21, Stewart et al teach a device for separating blood into blood components comprising a collecting container (16), a first satellite container (32) physically coupled to said collecting container (16) through a leukocyte filter (36) via a first conduit (26), a

second satellite container (28) physically coupled to said collecting container (16) through a leukocyte filter (36) via a second conduit and a third conduit (38) that bypasses the leukocyte filter (36), a plurality of valves (48, 49, 50, 52) that selectively control fluid flow between the containers including controlling fluid flow from the collection container (16) to the first satellite container (32) via the first conduit (26) that includes the leukocyte filter (36), controlling fluid flow from the collecting container (16) to the second satellite container (28) via the second conduit that includes the leukocyte filter (36) and controlling fluid flow from the second satellite container (28) to the collecting container (16) via the third conduit (38) that bypasses the leukocyte filter (36) (see figures 2-3; col. 4, line 49 – col. 8, line 37). Stewart et al further teach that the flow control means (48, 49) being further capable of allowing fluid flow from said second satellite container (28) into said collecting container (16) only through the bypass conduit (38) by opening clamp (49) and closing clamp (48) (see figures 2, 4; col. 8, lines 19-27).

Claim 21 essentially differs from the device of Stewart et al in reciting a leukocyte filter being configured to filter whole blood so as to remove leukocytes from the whole blood and allow platelets to pass therethrough. Stewart et al suggests that the transfer assembly (14) can be used to remove all types of undesired materials from different type blood cells, depending upon its particular construction (see col. 5, lines 19-22). Stewart et al teach a leukocyte filter that removes leukocytes and preferably also platelets from red blood cells prior to storage (see col. 5, lines 23-25). Nishimura teaches a device for separating blood into blood components including the leukocyte filter (1, 1') that removes leukocytes but allows platelets to pass therethrough to obtain leukocyte depleted PRP (see figures 5d, 6b; page 11, lines 5-7, 49-57). The claim would have been obvious because a particular known technique to use the leukocyte filter of Nishimura

in place of the leukocyte filter of Stewart et al to remove leukocytes but allow platelets pass therethrough to obtain leukocyte depleted PRP was recognized as part of the ordinary capabilities of one skilled in the art. In such configuration, manipulating flow control means (50, 52) e.g. closing one and opening the other to filter leukocytes from PRP or RBC in two separate steps would have been within the ordinary capabilities of one skilled in the art.

Regarding claim 22, Stewart et al teach a three-way conduit connector in the second satellite container conduit (see figure 2). Stewart et al teach that the first conduit (26) includes a first tubing segment that couples the collecting container (16) to the leukocyte filter (36), a second tubing segment that couples the leukocyte filter (36) to the first satellite container (32) through the three-way conduit connector and the second conduit including the first tubing segment that couples the collecting container (16) to the leukocyte filter (36), a third tubing segment that couples the leukocyte filter (36) to the second satellite container (32) through the three-way conduit connector and the third conduit (38) including a valve (49) operable in conjunction with the plurality of valves to control fluid flow from the second satellite container (32) to the collecting container (16) through the third conduit (38) (see figures 2-3). Claim 22 essentially differs from the device of Stewart et al in reciting a one-way valve in the third conduit. Stewart et al teach that the valves (48, 49) being further capable of allowing RBC from said second satellite container (28) into said collecting container (16) only through the bypass conduit (38) by opening clamp (49) and closing clamp (48) (see figures 2, 4; col. 8, lines 19-27). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate one-way valve in the third conduit between the second satellite container (28) and the collecting container (16) of Stewart et al to ensure bypassing of RBC from the

second satellite container (28) to the collection container (16 or 18) via third conduit (38) by the one-way valve.

Regarding claim 23, Stewart et al teach manually operated hose clamps (46, 47, 48, 50, 52, 54) (see col. 7, lines 29-33).

Regarding claim 24, Stewart et al teach a device for separating blood into blood components comprising a primary receptacle (16), a leukocyte filter (36), a first secondary receptacle (32), a second secondary receptacle (28), a set of flow controllers (48, 49, 50, 52) that selectively operable to provide: a first fluid pathway, wherein fluids flow from the primary receptacle (16) to the first secondary receptacle (32) through the leukocyte filter (36), a second fluid pathway, wherein fluids flow from the primary receptacle (16) to the second secondary receptacle (28) through the leukocyte filter (36), and a third fluid pathway, wherein fluids flow from the second secondary receptacle (28) to the primary receptacle (16) without passing through the leukocyte filter (36) (see figures 2-3; col. 4, line 49 – col. 8, line 37). Materials such as blood, PRP, PRC, WB in claim 1 worked upon by the device is not given patentable weight in the apparatus claims.

"Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 75 F.2d [illegible]996[illegible], 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Claim 24 essentially differs from the device of Stewart et al in reciting a leukocyte filter being configured to filter leukocytes and to allow platelets to pass therethrough. Stewart et al suggests that the transfer assembly (14) can be used to remove all types of undesired materials

from different type blood cells, depending upon its particular construction (see col. 5, lines 19-22). Stewart et al teach a leukocyte filter that removes leukocytes and preferably also platelets from red blood cells prior to storage (see col. 5, lines 23-25). Nishimura teaches a device for separating blood into blood components including the leukocyte filter (1, 1') that removes leukocytes but allows platelets to pass therethrough to obtain leukocyte depleted PRP (see figures 5d, 6b; page 11, lines 5-7, 49-57). The claim would have been obvious because a particular known technique to use the leukocyte filter of Nishimura in place of the leukocyte filter of Stewart et al to remove leukocytes but allow platelets pass therethrough to obtain leukocyte depleted PRP was recognized as part of the ordinary capabilities of one skilled in the art. In such configuration, manipulating flow control means (50, 52) e.g. closing one and opening the other to filter leukocytes from PRP or RBC in two separate steps would have been within the ordinary capabilities of one skilled in the art.

Regarding claim 25, Stewart et al teach that the second secondary receptacle (28) includes a blood additive "A" (see figure 2) and the flow controllers (49, 48, 50, 52) are capable of achieving claimed steps by sheer locations of the flow control means in the respective conduits (see figures 2-4). Note that claim 25 has method steps for flow controllers. Furthermore, Nishimura teaches that blood additive e.g. a preservative liquid for red cells may be contained in any of satellite bags 9, 9' and 9" and it is also preferred that the red cell preservative liquid be added to the red cell concentrate contained in bag 8 before the filtration (see page 10, lines 49-51). Flow controllers should be claimed as proper means plus function claim to consider the method steps with patentable weight. As presently claimed, the method steps in claim 25 with recitation of "in the following sequential order: the first fluid pathway … the

second fluid pathway... the third fluid pathway... through the leukocyte filter" is an intended use of the flow controllers. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claims 30, Stewart et al teach manually operated clamps (46, 47, 48, 50, 52, 54) (see col. 7, lines 29-33) associated with a separator device (36) and clamp (50) i.e. valve means in the second conduit means leading to the second satellite container (28) (see figure 2).

Regarding claim 32, Stewart et al teach a third secondary receptacle (30) connected in fluid flow communication with the first secondary receptacle (32) and a clamp (54) selectively operable to provide a fourth fluid pathway for fluid to flow from the first secondary receptacle (32) to the third secondary receptacle (30) (see figure 2).

6. Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al in view of Nishimura as applied to claim 24 above, and further in view of Corbin et al (WO 03/063930 A1). Stewart et al in view of Nishimura teaches a device for separating blood into blood components as described in above paragraph. Claims 26-29 essentially differ from the device of Stewart et al in view of Nishimura in reciting a sensor means controlling electromagnetic valve means for controlling the flow of components to respective satellite container by detection of the presence of blood component such as PRC. Corbin et al teach a device for separating blood into blood components comprising an optical sensor for detecting color of the blood components to close or open clamps (31, 32) on one or more branches (35, 36) to direct particular components to either a satellite bag (7) or a satellite bag (8) (see figure 5;

page 17, lines 1-21). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a sensor means to control electromagnetic valve means in the device of Stewart et al in view of Nishimura for controlling the flow of components to respective satellite container by detection of the presence of blood component such as PRC as suggested by Corbin et al (see figure 5; page 17, lines 1-21).

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart et al in view of Nishimura as applied to claim 24 above, and further in view of Bischof et al (US Patent No. 7,264,608 B2). Stewart et al in view of Nishimura teaches a device for separating blood into blood components as described in above paragraph. Claim 31 essentially differs from the device of Stewart et al in reciting a one-way valve provided in by-pass conduit allowing fluid flow only from second satellite container to collecting container. Bischof et al teach a device for separating blood into blood components comprising a one-way valve (V) provided in by-pass conduit (46) allowing fluid flow only from a satellite container (40) to collecting container (14) (see figures 2A-2B; col. 8, lines 32-47). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate a one-way valve provided in by-pass conduit in the device of Stewart et al in view of Nishimura for allowing fluid flow only from second satellite container to collecting container so to prevent fluid flow in opposite direction as suggested by Bischof et al (see col. 8, lines 43-47).

8. Applicant's arguments with respect to claims 21-32 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that Stewart et al does not suggest using a leukocyte filter twice to separate whole blood into two components, but uses a leukocyte filter only once to filter PRC.

Stewart et al teach a leukocyte filter that removes leukocytes and preferably also platelets from red blood cells prior to storage (see col. 5, lines 23-25); hence, PRP by-passes the leukocyte filter. Nishimura teaches a device for separating blood into blood components including the leukocyte filter (1, 1') that removes leukocytes but allows platelets to pass therethrough to obtain leukocyte depleted PRP (see figures 5d, 6b; page 11, lines 5-7, 49-57). The claim would have been obvious because a particular known technique to use the leukocyte filter of Nishimura in place of the leukocyte filter of Stewart et al to remove leukocytes but allow platelets pass therethrough to obtain leukocyte depleted PRP was recognized as part of the ordinary capabilities of one skilled in the art. In such configuration, manipulating flow control means (50, 52) e.g. closing one and opening the other to filter leukocytes from PRP or RBC through the leukocyte filter in two separate steps would have been within the ordinary capabilities of one skilled in the art. Such configuration inherently avoids PRP bypassing the leukocyte filter.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN KIM whose telephone number is (571)272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Kim/
Primary Examiner, Art Unit 1777

JK
1/8/11